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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,866	06/04/2001	Mark K. Hechinger	1007-103.US	4668

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EXAMINER
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CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/873,866	<b>Applicant(s)</b> HECHINGER, MARK K.	
	<b>Examiner</b> Jacob Cheu	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Applicant's amendment filed on 8/19/2004 has been received and entered into record and considered.

Claims 1-19 are currently under examination.

Claims 20-25 are withdrawn from further consideration.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1-19, 26 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Adding surfactant and prewashing steps are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim 1 recites a feature "washing the beads in the buffer to form bead-buffer matrix and reducing the surfactancy of the beads to no more than 5% to allow antigen to attach to the beads." In the specification applicant asserts that "the surfactant amount or the amount of chemical stablizer used by the bead manufacture to prevent clumping, within the stock solution should not exceed 5% in the initial stock solution" (See page 20, second paragraph, emphasis). It is known in the art that using surfactant to reduce surfactancy. Nevertheless, it is not positively recited in the claim language which leaves the buffer-

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bead matrix for reducing surfactancy. It is not likely that mere buffer-matrix would render such an effect on surfactancy. Since it is a critical and essential step for the feature of “reducing the surfactancy no more than 5% to allow antigen to attach to the beads”, applicant needs to incorporate adding surfactant step to fulfill enablement requirement in the claim language.

Similarly, applicant asserts that the prewashing steps “are very important and significant to the invention, since the prewashing removes surfactants and helps to prevent the clumping of the beads during the assay and flow cytometry” (See page 25, third paragraph; page 31, second paragraph)(emphasis added). It is critical and essential to have this “prewashing step” to remove surfactant and prevent clumping of the beads. Applicant needs to incorporate this prewashing step in the claim language to fulfill the enablement requirement.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-19, 26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between steps. See MPEP 2172.01.

The omitted steps are “adding surfactant” and “prewashing” steps as discussed above.

*Response to Applicant's Arguments*

*Reducing Surfactancy of beads*

1. Applicant argues that “[t]he position of the step is important although it is submitted that the manner of reducing surfactancy would be known” (See Remarks, page 6, (2) paragraph). Applicant’s argument has been considered but is not persuasive. It is known in the art that using surfactant to reduce surfactancy. However, the claim language is silent in this respect. The language implies that the mere bead-buffer matrix is capable of reducing the surfactancy of the beads which is not true. Applicant needs to positively recite this important step into the recited method.

*Prewashing Step*

2. Applicant argues that the prewashing steps help to reduce the surfactancy to the level of “no more than 5%” of surfactancy (See Remarks, page 6, (3) paragraph). Applicant’s argument has been considered but is not persuasive. As indicated in this Office Action, the preamble of the instant invention directs to a “no wash” bead based assay. If the “prewashing step” is to “help to reduce the surfactancy to the level claimed”, this would be inconsistent with the purported preamble. Furthermore, claim 17 also recites “wherein the bead-buffer matrix is subject to at least one prewashing step”. Therefore, “washing” is actually needed for this bead based assay. Furthermore clarification is required to resolve this issue.

*Conclusion*

3. No claim is allowed.
4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

Art Unit 1641

November 16, 2004



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

11/29/04